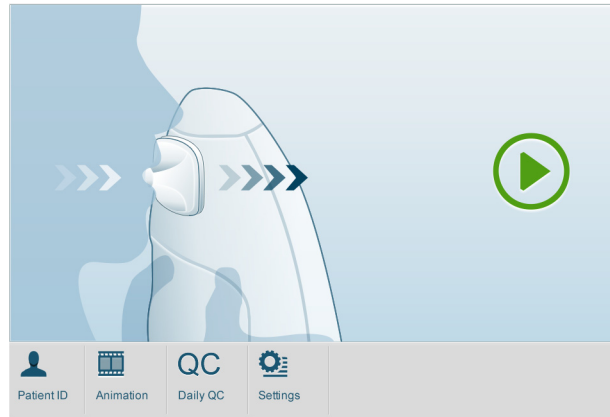


NIOX[®] Panel

PC application for NIOX MINO[®]

User Manual



CE

Aerocrine

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1 Important information

NIOX® Panel is a visual aid for operating NIOX® MINO Airway Inflammation Monitor by allowing the user to operate the NIOX MINO from their PC.

1.1 Before using NIOX® Panel

NIOX® Panel PC application (NIOX® Panel) shall only be operated as directed in this manual by trained healthcare professionals. Trained status is achieved only after careful reading of this manual. Read the entire instructions for use and make certain that you fully understand the safety information. The NIOX MINO User Manual describes how to use the device.

Symbol	Description
WARNING!	Indicates a potentially hazardous situation that, if not avoided, can result in bodily harm or injury.
CAUTION!	Indicates a potentially hazardous situation that, if not avoided, can damage a product or system, cause loss of data or harm to business.
Note	Alerts the reader to important information on the proper use of the product, user expectations, error situations, and actions related to these.

1.2 About this manual

NIOX® Panel User Manual - US 000200 (EPM-000194), version 02, May 2015, for application with version number 1.0.X.X and instruments with software version 23XX. To view version number for your instrument, refer to NIOX MINO User Manual. For instruction on how to update firmware see page 6.

Information in this document is subject to change. Amendments will be made by Aerocrine AB as they occur.

- Aerocrine, NIOX and NIOX MINO are registered trademarks of Aerocrine AB.

1.3 Responsible manufacturer and contacts

Mailing address:

Aerocrine AB
P.O. Box 1024
SE-171 21 Solna, Sweden

Visiting address:

Råsundavägen 18
SE-169 67 Solna, Sweden

www.aerocrine.com
www.niox.com

1.4 Warnings

- NIOX® Panel shall only be operated by healthcare professionals.
- Operate NIOX® Panel as stated in this manual. Aerocrine accepts no responsibility for damaged equipment or faulty results, if the equipment is not handled according to this manual.
- When selecting an accessory for your NIOX® Panel product keep in mind that an accessory not recommended by Aerocrine may result in loss of performance, damage to your NIOX Panel product, fire, electric shock, injury or damage to other property. The product warranty does not cover product failure or damage resulting from use with non approved accessories. Aerocrine takes no responsibility for

health and safety problems or other problems caused by the use of accessories not approved by Aerocrine.

- Modification of NIOX® Panel application is not allowed.
- Do not use damaged components.
- Do not disconnect the instrument during firmware loading.
- The patient filter is for single use only.
- All warnings in the NIOX MINO User Manual are also applicable.

1.5 Intended use

NIOX® Panel is an optional software accessory allowing an additional display for the NIOX MINO® Airway Inflammation Monitor

Refer to the NIOX MINO® User Manual for NIOX MINO® intended use.

1.6 Training requirements

NIOX® Panel shall only be used as directed in this manual by trained healthcare professionals. Trained status is achieved only after careful reading of this manual.

The User Manual provides instructions on how to operate NIOX® Panel. It contains numbered step-by-step instructions with screens and illustrations. Choices within steps are displayed with bullet points.

2 Installation and setup

2.1 Installation

NIOX Panel System requirements

- Windows® XP*(32 bit), Windows® Vista(32 bit), Windows® 7 or Windows® 8.0/8.1 Pro (RT versions excluded)
- .NET Framework 4.0
- 1 GHz or faster processor
- 256 MB RAM (512 MB RAM recommended)
- 250 MB of video graphics RAM
- 250 MB of available hard-disc space
- 1024x768 screen resolution

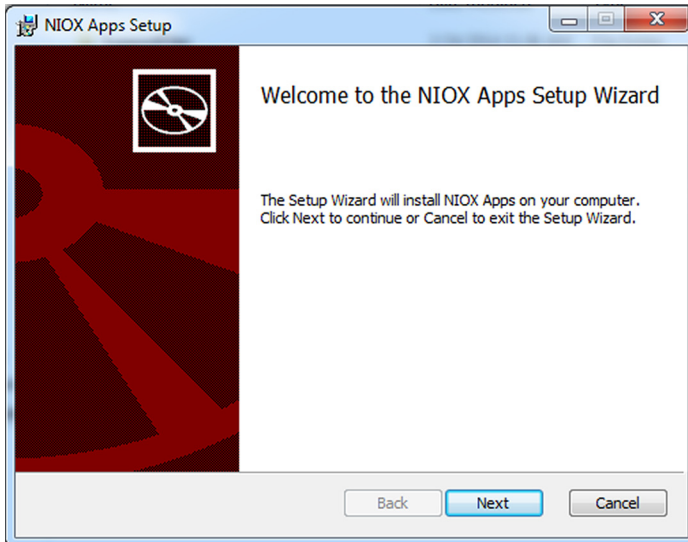
* Windows XP with Service Pack 3

Note: *If the computer does not fulfill the system requirements, see note on page 10.*

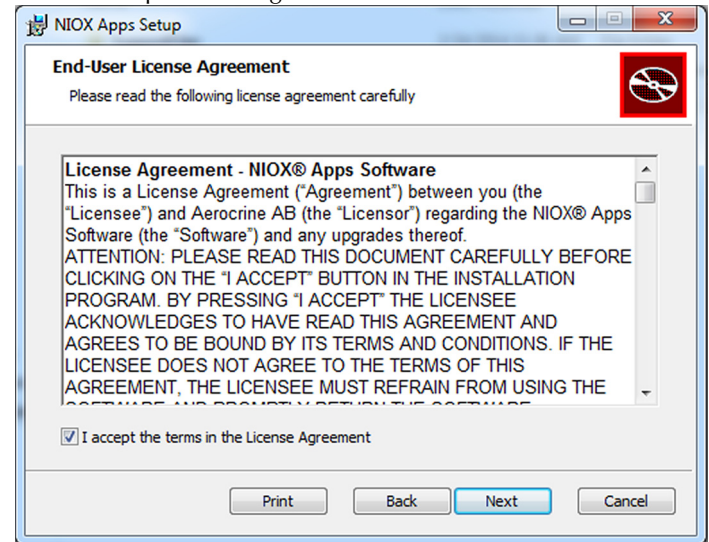
The NIOX® Panel software is supplied on a USB storage device.

1. Insert the USB storage device in the computer's USB port.
2. In the folder NIOX Panel 1.0.X.X select the file named **setup.exe**
3. If .NET Framework 4.0, VC++ 2010, XNA or SQL Server Compact is not installed, an installation wizard for each of the programs opens, one at the time.
4. Select **Yes**.
5. Select **Accept** license agreement.

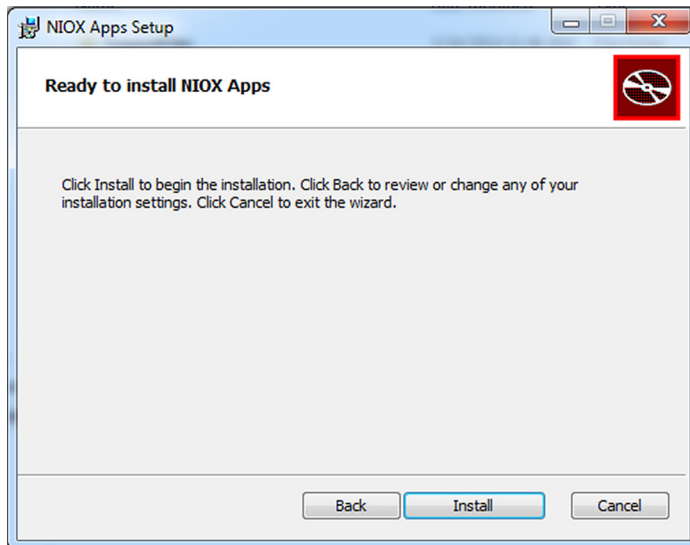
6. Wait until the programs are installed.
7. The Installation wizard for NIOX® Panel opens. Click **Next**.



8. Select Accept license agreement.



9. Accept or select a different folder for the program. Then select to allow NIOX® Panel to be accessible for only yourself (logged in) or everyone who logs in on the same computer. Click **Next**.
10. Start the installation by clicking **Next**.



11. Wait until the installation is finished.
12. When the installation is complete, click **Finish**.
13. The application is now available on the start menu.

2.2 Setup

Note: In order for the NIOX® Panel to be able to communicate with NIOX MINO®, a USB cable is needed. Only USB cables supplied by Aerocrine may be used.

2.2.1 Connect the instrument via USB

1. Turn on the PC and monitor.
2. Plug the USB cable into the USB port on the instrument and connect it to the USB port on the PC.



The  icon is shown on the display to indicate that a connection is established and NIOX MINO® is running remote controlled.

Note: It may take a few seconds for the connection to establish.

3. Select the **Start** or the **Windows** button normally found in the left lower hand corner of your monitor.
4. Select **NIOX Panel** from the program list.

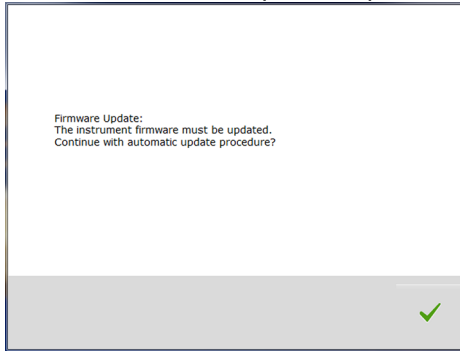
2.2.2 Firmware update

Note: If NIOX MINO firmware is a version < 23XX the instrument must be updated.

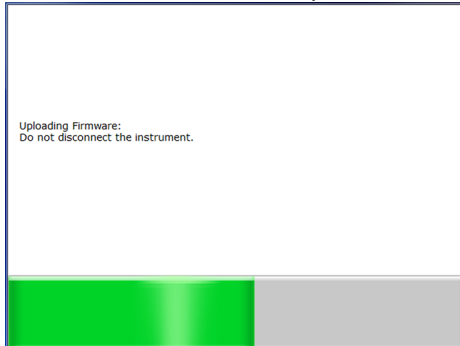
Note: If the firmware version is 2005 or earlier contact Aerocrine Customer Support.

Note: Always connect the instrument by USB cable for firmware update.

1. A view for automatic update is opened.



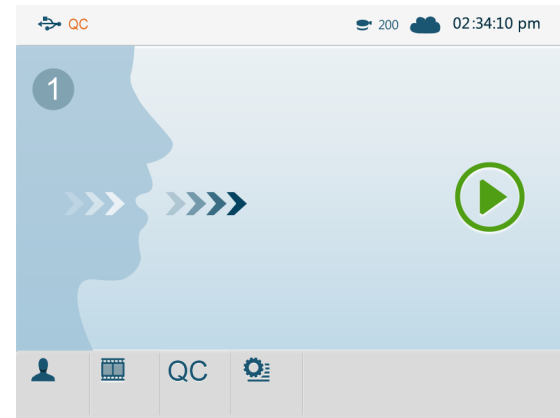
2. Press OK and wait for the upload to finish.



CAUTION! Do not disconnect the instrument during load of firmware.

3. When the firmware has been uploaded the instrument will disconnect and perform an internal update, after completion the instrument will reconnect automatically.
4. The NIOX Panel opens.

Note: When starting NIOX Panel for the first time the connectivity details dialog box opens



2.2.3 NIOX Panel connectivity module

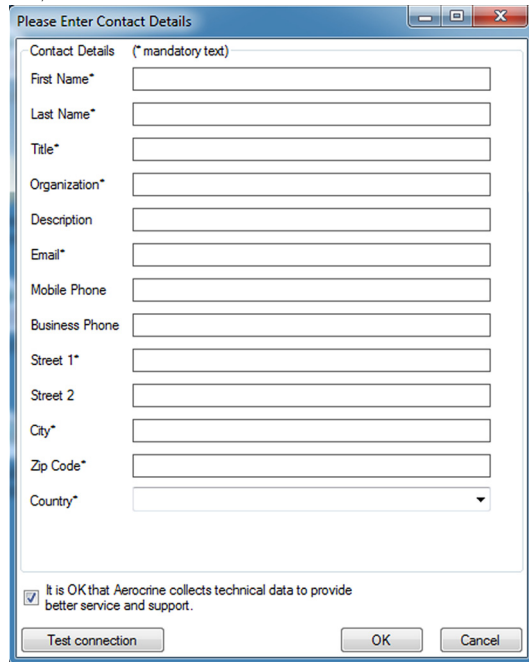
The connectivity module in NIOX Panel utilizes Microsoft's secure cloud service, Microsoft Azure, to automatically transmit technical data from the device via the internet to Aerocrine.

Technical data such as time stamp, alert codes and number of remaining measurements on the device and sensor are received. This information will ensure better service and support.

Chapter 2 Installation and setup

Aerocrine recommends completion of the details dialog box to allow receipt of technical data and provide better service and support functions to its customers.

Mandatory fields are marked with a *. Complete these, leave the box checked, and click OK to continue.



When connection to Microsoft Azure is established a cloud icon  is shown in the status bar.

If the connection to Microsoft Azure is lost or the user has chosen to not send technical data, the cloud icon is crossed over .

To decide at a later stage to allow Aerocrine to collect data, press cancel and the dialog box will open again next time NIOX Panel is started, or click on the cloud icon in the status bar.

To reject collecting of Aerocrine technical data (not recommended) uncheck the box in the bottom of the window and click OK.

Note: Only technical data and no patient data is collected by Aerocrine.

Changing contact details

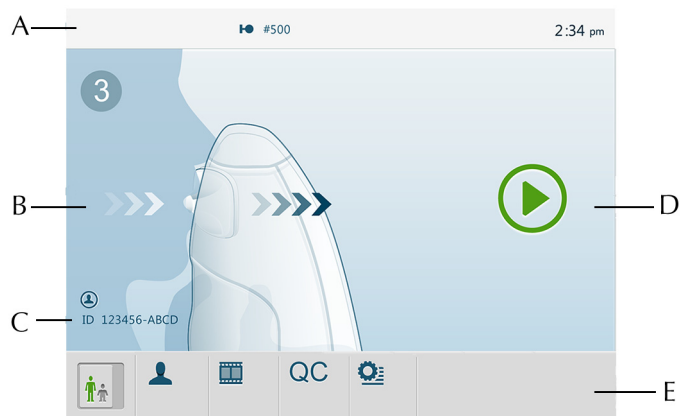
To edit contact details click on the cloud icon  in the status bar to open the contact details dialog box.

3 Navigation

3.1 Interface

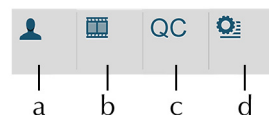
This section describes the main view. Buttons and symbols are further described on page 23.

3.2 Main view



(A) Status bar (time, sensor info and alert), (B) Animation in three steps, (C) Patient ID (if entered), (D) Start measurement button, (E) Main menu

3.2.1 Main menu



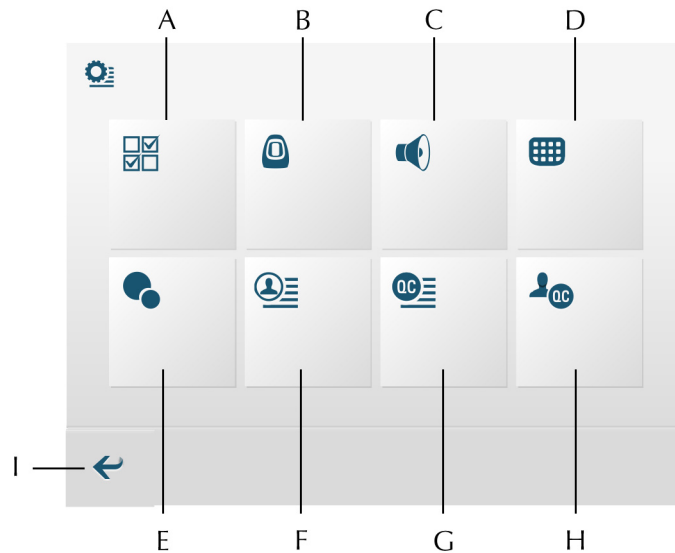
(a) Patient ID entry, (b) Demo, (c) Quality Control, (d) Settings

3.2.2 Status bar



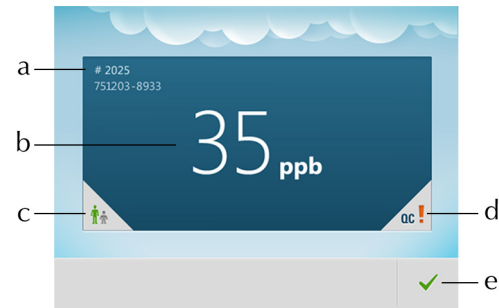
(a) USB icon, (b) QC warning, (c) Scrubber symbol (about to expire or has expired-blinking), (d) Instr symbol (about to expire or has expired-blinking), (e) Sound mute, (f) Remaining measurements on Sensor, (g) Connected to Microsoft Azure, (h) Time

3.2.3 Settings view



(A) User Settings, (B) Device info (see page 14), (C) Volume (see page 13), (D) Scrubber info (see page 15), (E) Ambient measurement (see page 13), (F) Patient log (see page 15), (G) QC log (see page 19), (H) QC info (see page 19), (I) Return to main view

3.2.4 Measurement view



(a) Measurement sequence number, (b) FeNO value in ppb (parts per billion), (c) Measurement mode 10 seconds exhalation time, (d) QC alert (if not performed the current day), (e) OK - returns to main view

4 Using NIOX® Panel

4.1 Register patient ID (optional)

Note: If Patient ID is used, it has to be entered before each measurement, even if it is the same patient. Local Regulations on Patient information privacy must be considered when using unique patient identifiers.

1. Select the **Patient ID** button from the main menu.
2. Enter up to 12 characters (alpha or numeric).



4.2 Measure FeNO

Verify proper operating conditions before performing a measurement with NIOX MINO®. A basic preventive inspection is recommended before each use (see page 22). Make sure a successful daily QC is performed, see page 17. Refer to NIOX MINO User manual for more detailed directions.

4.2.1 Perform FeNO measurement

WARNING! The patient filter is for single use only.

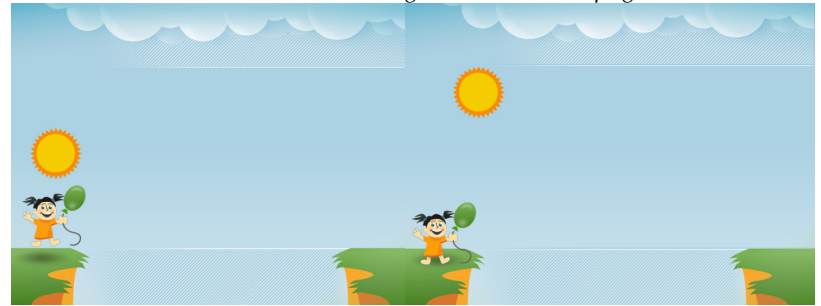
1. Attach a new patient filter.
2. Turn the PC-monitor facing the patient.
3. Select **Start measurement** button on the display.



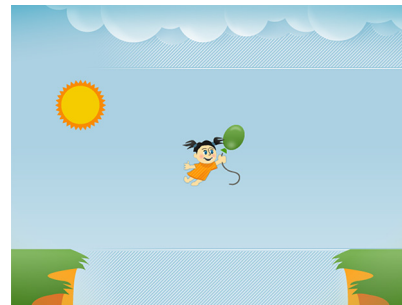
Note: If the computer does not fulfill the system requirements it may still be possible to run NIOX Panel.
To start a measurement select the Win XP animation.
It is recommended to press the “start measurement” button to initiate the measurement.

4. Instruct the patient to perform steps 5-8.
5. Empty lungs.
6. Close the lips around the NIOX MINO® patient filter so that no air leakage occurs.
7. Inhale deeply through the filter.
The screen shows an animation where the sun rises.

Note: There are three optional animations (Cloud, Balloon or Meter). For instructions on how to change animation see page 12.



8. Exhale slowly through the filter while keeping the balloon within the limits as indicated on the screen (the white lines).



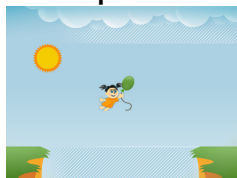
9. The visual incentive, instruments- audio signals and top light guide the user to the correct exhalation pressure.

A continuous sound indicates correct pressure with a frequency proportional to the pressure.

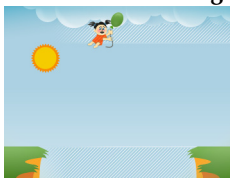
- An intermittent high frequency sound - too strong pressure
- An intermittent low frequency sound - too weak pressure

Exhalation with:

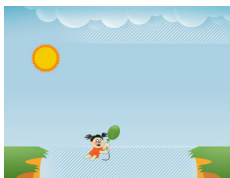
Correct pressure



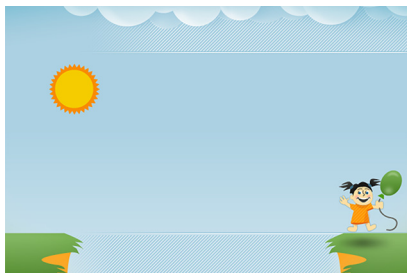
Pressure too strong



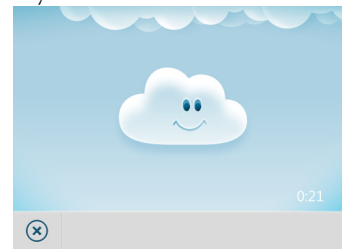
Pressure too weak



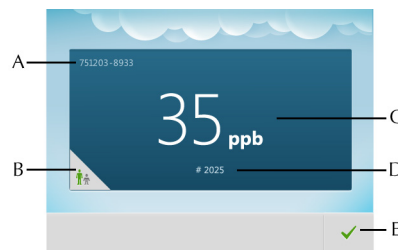
10. Exhale until the balloon has reached the end of the screen.



The instrument will analyze the sample and generate a result in approximately one and a half minutes.



CAUTION! Do not disconnect the instrument from the PC during measurement and analyzing process.



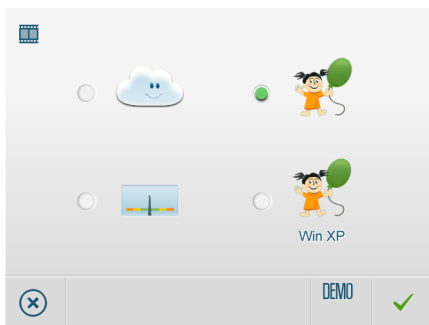
(A) Patient ID - if applicable, (B) Measurement mode, (C) FeNO value in ppb (parts per billion), (D) Measurement sequence number, (E) OK - returns to main view

11. Remove the patient filter.

4.3 Demonstration mode

To help professionals in guiding patients, NIOX Panel contains an animated demonstration with a visual guide of the different stages of a measurement procedure.

1. Select the **Animation** button on the main menu. A view to select demo animation appears.
2. Select which animation mode you which to use. Then select **DEMO**.



3. Select the **Forward** button to move to the following sequence.

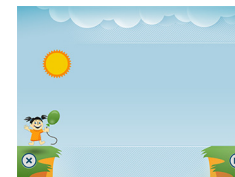
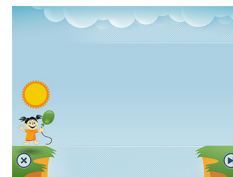


4. Select OK to confirm the changes. 

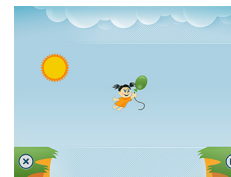
The **Close** button returns to the main menu.



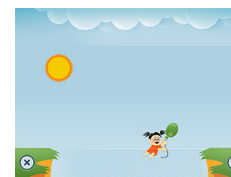
- a. Inhalation through the patient filter.
The sun rises.



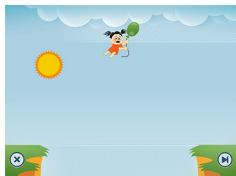
- b. Exhalation through the patient filter with correct pressure.



- c. Exhalation through the patient filter with pressure too weak.



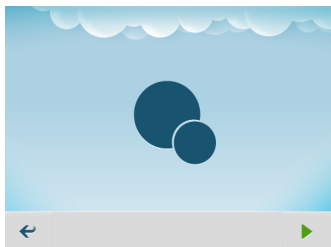
- d. Exhalation through the patient filter with pressure too strong.



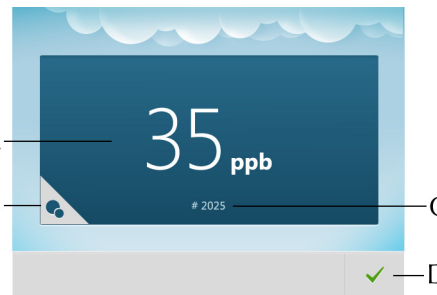
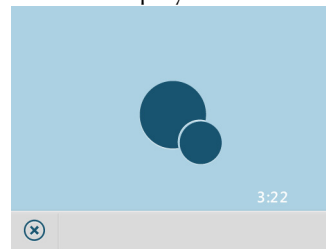
4.4 Measure ambient NO

Note: An ambient measurement is counted as one measurement on NIOX MINO® Sensor and the instrument.

1. Attach a patient filter.
2. Select the **Settings** button on the main menu.
3. Select **Ambient Measurement** button.
4. Select the **Start Ambient measurement** button.



5. The analyzing view is visible until the measurement is finished and the result is displayed.



- (A) Ambient measurement value (in ppb), (B) Measurement mode, (C) Measurement sequence number, (D) OK - returns to main view

4.5 Change settings

4.5.1 Change volume

1. Select the Settings button on the main menu.
2. Select the Volume button.



3. Select the decrease/increase to adjust volume. 
4. Select the Return button to confirm changes and return to settings. 

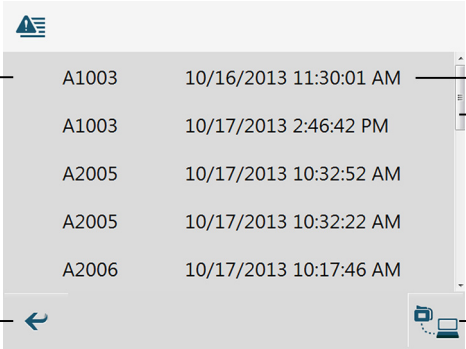
Note: The status bar indicates mute status when the sound volume is set to zero. 

4.5.2 View alert logs

Alerts are stored in the instrument, and can be viewed at any time. The alert codes are for use by Aerocrine Customer Support.

1. Select the **Settings** button on the main menu. 
2. Select the **Device info** button. 
3. Select **Alert log** button. 

Note: It may take a few seconds to load all alert codes.



A	A1003	10/16/2013 11:30:01 AM	C
	A1003	10/17/2013 2:46:42 PM	D
	A2005	10/17/2013 10:32:52 AM	
	A2005	10/17/2013 10:32:22 AM	
	A2006	10/17/2013 10:17:46 AM	
B			E

(A) Alert code, (B) Return button - returns to settings view, (C) Date of alert, (D) Scroll bar, (E) Download service data (only upon request by Aerocrine)

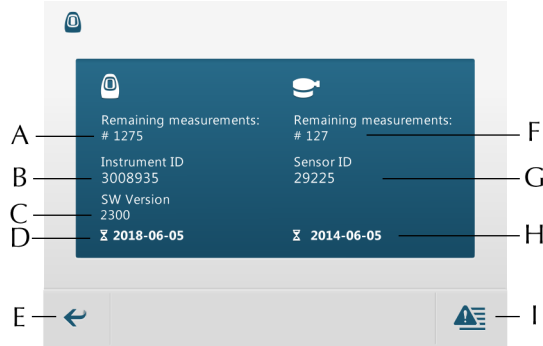
4. Select the Return button to return to settings. 

4.5.3 View instrument information

Detailed information about the instrument and Sensor can be viewed.

1. Select the **Settings** button on the main menu. 
2. Select the **Device info** button. 

3. This opens the Instrument information view displaying the following:



(A) Numbers of remaining measurements on the instrument, (B) Instrument serial number, (C) Instrument software version, (D) Instrument expiration date, (E) Return to settings, (F) Numbers of remaining measurements on the Sensor, (G) Sensor serial number, (H) Sensor expiration date, (I) Alert log button

4.5.4 View patient measurement logs

All measurement results are stored in the instrument and can be viewed at any time.

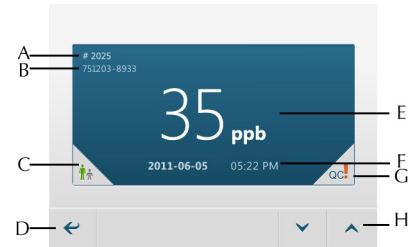
1. Select the **Settings** button on the main menu.



2. Select **Patient log** button.



3. This opens the **Record view**. The log will display the following:



(A) Measurement sequence number, (B) Patient ID - if entered, (C) Measurement mode, (D) Return to settings, (E) FeNO value, (F) Measurement date and time, (G) QC Alert, (H) Forward, Backward

4. Browse through the measurement logs using the forward and backward buttons.



Select the Return button to return to settings.



4.5.5 View scrubber information

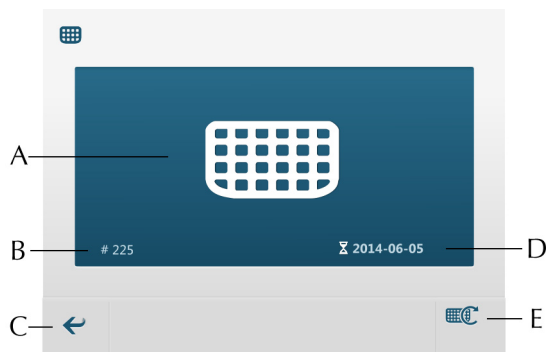
1. Select the **Settings** button on the main menu.



2. Select the **Scrubber** button.

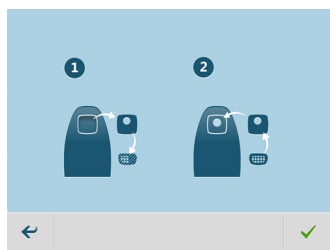


The **Scrubber information view** opens.



(A) Scrubber icon, (B) Number of measurements left on Scrubber, (C) Return button, (D) Expiration date on Scrubber, (E) Change scrubber button

3. If all measurements on the Scrubber have been used, select the Change Scrubber button.
4. The Change Scrubber view opens.
5. Change Scrubber as instructed and select OK to verify.



4.6 External Quality Control (QC) procedure

The external Quality Control is one of the procedures that ensures the system is operating within its specifications.

Note: *The Quality Control function in NIOX MINO must always be activated as a daily QC measurement is mandatory when the instrument is clinically used.*

A QC icon in the status bar **QC** on the screen indicates that a daily external QC assessment is needed or that there are not any currently qualified QC individuals who have completed their initial 4 qualification attempts.

The external Quality Control consists of two parts. One positive control from a qualified staff member with a stable FeNO value providing a normal biological FeNO sample and a negative control consisting of a NO free gas sample, generated from ambient air.

To perform QC measurements with NIOX Panel a connection to the NIOX database is needed. This makes it possible to create the QC users and store the QC measurements in the database. For instructions on creating QC users in the database see NIOX Patient User Manual.

Performing the QC measurements with NIOX Panel gives the QC User (after qualification) the opportunity to qualify a new instrument with just one measurement or several instruments on the same day.

4.6.1 Selection and qualification of QC testers

A minimum of one individual (two individuals are recommended) needs to qualify for this procedure. If possible, identify a third individual as a back-up.

Identify the staff members who will perform the Quality Control and meet the following criteria:

- Over 18 years of age.
- No ongoing cold or known airway disease.
- Non-smoker.
- Expected stable FeNO values between 5 and 40 ppb.
- Preferably no allergies (except seasonal, see below) or asthma.

A QC tester will be qualified over the course of four days within a seven day period.

Note: *After a QC tester has been qualified, if the most recent QC measurement is older than 30 days, then the qualification is suspended and the QC tester needs to re-qualify according to the qualification procedure. Perform four QC measurements, one per day within seven days, according to the QC measurement section, in order to qualify a QC tester.*

A mean value is calculated from the three qualifying measurements that must be between 5-40 ppb for the QC tester to be qualified. The QC measurement on the fourth day (daily QC) must be within ± 10 ppb from the mean value and the negative control approved. If this has been met the Quality Control has passed for that staff member and the instrument is ready for clinical use. The moving mean value is recalculated when the QC tester performs a QC measurement after seven days.

4.6.2 QC measurement

This procedure applies for qualification and daily QC measurements. The instrument will prompt for a daily QC procedure by showing **QC** in the status bar. Always consider the following in order to obtain reliable results.

Before any measurement:

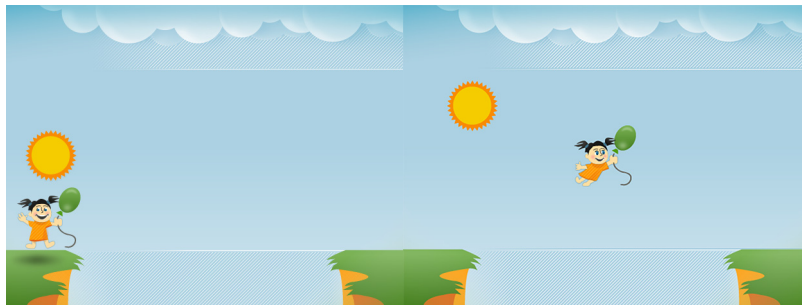
- Avoid nitrate rich food within 3 hrs before the measurement.

- Avoid strenuous exercise at least 1 hour before the measurement.
- Preferably do not perform a measurement in case of:
 - Ongoing cold.
 - Acute seasonal allergy.
- Always attach a new patient filter for each new QC tester.

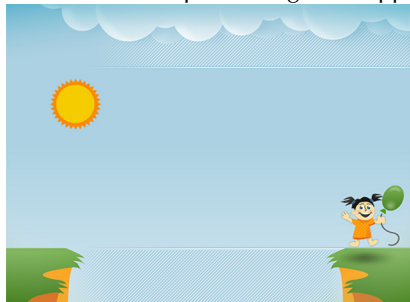
1. Select **QC**.



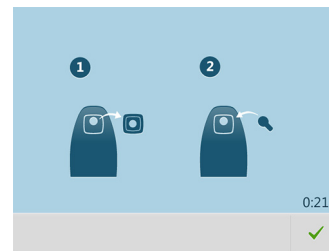
2. Select the correct **QC User**.
3. Empty lungs.
4. Close the lips around the NIOX MINO® patient filter so that no air leakage occurs.
5. Inhale deeply through the filter. The screen shows an animation where the sun rises.



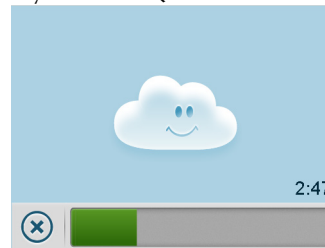
6. Exhale slowly through the filter until the balloon reaches the end of the screen. The processing view appears.



7. Remove the patient filter and immediately attach the QC plug.



8. Press  to proceed.
9. The process indicator is visible until the measurement has been analyzed. The QC control result is displayed.

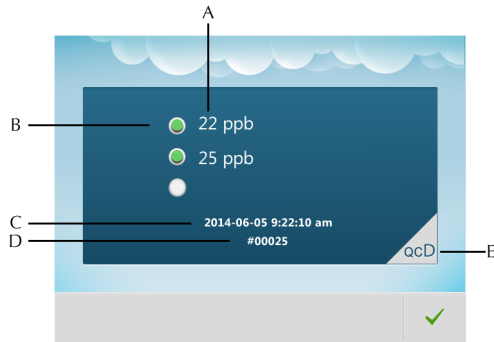


(A) QC user limits (mean value +/- 10 ppb), (B) Control result in ppb, (C) QC measurement sequence number, (D) QC measurement date and time, (E) QC user (database user)

10. Remove the QC plug.

Note: Press  to return to main menu.

During the qualification days of a new QC tester the result is displayed as presented below.



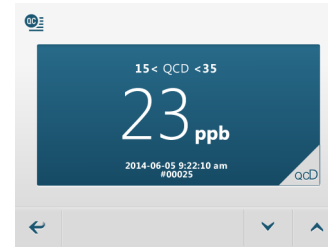
(A) Measured NO value in ppb, (B) Status button (green = within specifications, white = not within specifications), (C) Date of measurement, (D) QC measurement sequence number, (E) QC user

Press  to return to main menu.

Repeat the QC test if the positive and/or the negative control fails. If the QC failure persists, discontinue use of NIOX MINO® and contact Aerocrine Customer Support.

4.6.3 View QC logs

1. Select the **Settings** button on the main menu. 
2. Select the **QC log** button. 
The QC log window opens.



3. Browse through the measurement logs using the backward and forward buttons. 

4.6.4 View QC information

After day 3 the QC qualification procedure is ended. A qualified tester is displayed in the QC info view

1. Select the **Settings** button on the main menu. 
2. Select **QC info** button. 

3. The QC qualifying results are displayed as follows.

A	B	C
Mary Smith	2014-12-25	12ppb
Carol Tell	2014-12-12	14ppb
Johnny Miller	2015-01-01	22ppb
John Norman	2014-12-22	25ppb
Ken Parker	2014-12-02	19ppb
Christin Harward	2014-12-10	15ppb

D ←

(A) QC User name, (B) Date for latest moving mean calculation, (C) Mean value in ppb, (D) Return button

Select the Return button to return to settings. ←

4.7 Turn off NIOX® Panel

To turn off NIOX Panel, select the **Exit** button in the top right corner.

5 Troubleshooting

5.1 Alert codes and actions

Alert messages and other information are shown as a code on the instrument display. The tables below provide the alert codes and recommended actions to be taken for an alert code. If the alert persists, contact your local Aerocrine representative or Aerocrine Customer Support.

User alerts	Action
A10	Exhalation too strong. Repeat the measurement with less strength.
A11	Exhalation too weak. Repeat the measurement with greater exhalation force.
A12	No exhalation detected. Repeat the measurement and exhale into the instrument directly after inhalation.
A13	Analysis interrupted. Repeat the measurement and do not breathe through the patient filter during analysis.

QC alerts	Action
A50	The mean value of the three qualification results does not fall between 5-40 ppb. Restart the QC tester qualification from qualification day 1.

QC alerts	Action
A51	There has been an attempt to perform several QC measurements at the same day with the same test person. Wait one day and perform the next QC measurement.
A52	Moving mean value out of range. Restart the QC tester qualification from qualification day 1.
A53	NO scrubber result over 5 ppb. Check that the QC Plug was attached when instructed. Restart the QC measurement. If continuously shown replace the NO scrubber.
A54	Daily QC result lower than 5ppb. Restart the measurement with a test person who has a FeNO value higher than 5 ppb.
A55	Daily QC result higher than 40 ppb. Restart the measurement with a test person who has a FeNO value lower than 40 ppb.
A56	Failure to press the QC plug forward button in time (within 1:30 min). Repeat the QC measurement and make sure to press the forward button after the QC plug is inserted.

Instrument alerts	Action
A20	Ambient temperature alert Check that the ambient temperature is within specification. If necessary, move the instrument to another location and restart the instrument.

Instrument alerts	Action
A21	Remove any sources of disturbance (such as cordless phones/mobile phones or gas emitting appliances). When the instrument is ready for use repeat the measurement. If alert persists, unplug and connect the power supply unit to restart the instrument.
A22	Unplug and connect the power supply unit to restart the instrument.
A23	Remove any sources of disturbance (such as cordless phones/mobile phones or gas emitting appliances). When the instrument is ready for use repeat the measurement. If alert persists, unplug the power supply unit, remove and insert the Sensor and restart the instrument.
A24	Check that the supply voltage is within specification. If necessary replace the power supply unit.
A31	Check the USB connection with the PC.
A90	Instrument expiration date has passed or all instrument measurements have been used. It is still possible to view measurements stored in the instrument memory and download data to a PC. Contact Aerocrine.
A91	Sensor expiration date has passed or all measurements on the Sensor have been used. Replace the Sensor.

6 Preventive inspections

Refer to the NIOX MINO® user manual for details on how to perform preventive inspections.

If the application is not working properly contact your local Aerocrine representative or Aerocrine Customer Support.

7 Safety information

7.1 Cautions

- Make sure that you use the correct measurement mode, otherwise incorrect exhaled FeNO results might be obtained.
- Do not disconnect the instrument during measurement and analyzing process.

7.1.1 Limited warranty

Aerocrine provides a Limited Warranty for this application. Conditions are defined when the items are purchased.

Do NOT try to repair the application. Any attempt will make the warranty invalid and performance according to the specifications cannot be guaranteed.

7.1.2 Support

Contact Aerocrine Customer Support if you encounter problems, which you cannot solve with the information in this manual.

For contact details, see back cover, and provide the following information:

- Your name, address and telephone number.
- Serial number for both the application, instrument and Sensor.
- Problem description (as thorough as possible).
- Alert codes or lists.

8 Buttons and descriptions

8.0.1 Control buttons

	OK - accept changes/verify result		Reset scrubber
	Undo - closes view without saving changes		Start 10s measurement
	Return		Start ambient measurement
	Forward-move to the following sequence		Demo
	Decrease/step backward		Radio buttons - not performed/performed
	Increase/step forward		Download service data
	Check box (not active)		Alert log
	Check box (active)		

8.0.2 Main menu buttons

	Animation		Patient ID
	QC		Settings

8.0.3 Settings view buttons

	User settings		Patient log
	Volume		Ambient measurement
	Device info		Scrubber info
	QC info		QC log

8.0.4 Status bar

	02:34 pm Time		200 Sensor status - followed by number of measurements remaining. About to expire or has expired (blinking)
	Instrument connected via USB		Instrument- about to expire or has expired (blinking)
	Scrubber - about to expire or has expired (blinking)		Audio - mute
	QC Indicates that no QC measurement is performed the current day		
	Connected to Microsoft Azure		Not connected to Microsoft Azure

8.0.5 Display

	Result screens - 10 s mode
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Information in this document is subject to change.

Amendments will be made available by Aerocrine AB as they occur.

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Based on the company's intellectual property, Aerocrine develops and commercializes products for the monitoring of nitric oxide (NO) as a marker of inflammation, to improve the management and care of patients with inflammatory disease in the airways.

Patents:

For information about patents relating to Aerocrine products see www.aerocrine.com

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